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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HUANG, GIGI GEORGIANA

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

10/29/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/530,598	Applicant(s) HAREL ET AL.	
	Examiner GIGI HUANG	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-48 and 57-72 is/are pending in the application.
- 4a) Of the above claim(s) 35-48 and 57-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 60-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/16/2009, 8/26/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

1. The response filed June 15, 2009 has been received, entered and carefully considered. The response affects the instant application accordingly:
 - a. Claim 60 has been amended.
 - b. Claim 49-56 has been cancelled.
 - c. Claim 65-72 has been added.
2. Claims 35-48, 57-72 are pending in the case.
3. Claims 60-72 are present for examination.
4. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.
5. All grounds not addressed in the action are withdrawn or moot.
6. New grounds of rejection are set forth in the current office action.

New Grounds of Rejection

7. Due to the amendment of the claims the new grounds of rejection are applied:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 66 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is directed to utilizing different mixing methods for mixing carotenoids and phospholipids such as vortex mixing, high shear mixing,

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sonication, and molecular level mixing. First, it is unclear what molecular level mixing encompasses and mixing sugar in tea will result in a molecular mixture of the sugar and tea. The claim is also unclear as the specification addresses mixing the two components to form a composition which appears to be further dried and processed to form a powder (demonstrated by Example 1 in Page 14), but not with another animal feed component which would be directed to a different composition than what is claimed (e.g. the premix). This is supported by Example 1 which combines the phospholipid (not from algal) and the carotenoid, mixed with a solvent (ethanol), and then dried to evaporate the solvent yielding a powder which is a different composition. While it can be utilized for other uses, it would need to be dissolved in oil for coating wherein it is confusing as there are steps missing to be supported by the specification if taken in this vein. It is also confusing as the specification states that for the solvent to be utilized for the mix, the phospholipids would have to be de-oiled which is not commensurate in scope with the claims and may be subject to new matter; as the oiled phospholipids would simply be combined with the carotenoid and mixed. It is unclear what steps are intended and what would be supported by the specification. For purposes of prosecution, use of any commercial mixer at any point applies.

9. Claim 71 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is directed to further comprising a polar solvent consisting of chlorocarbons and lower alcohols. As addressed above, it is unclear how or where the solvent is placed in the method. The solvent is only described in the

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specification with a de-oiled phospholipid and only demonstrated as to the formation of the premix powder which would be for purification and is not what the claim is directed to. There isn't support for the solvent as part of the resulting feed composition and as it is also added to coating feed in other claims, it appears to be the oiled phospholipid as the de-oiled form would need to be reconstituted prior to combining in the instant specification. It is also confusing as use of a solvent to derive either the phospholipid or carotenoid is common in the art for extraction of these materials from biomasses or live organisms whereby it is unclear what the role of the solvent is in the method of the claim. For purposes of prosecution until appropriate clarification, the use of the solvent at any point applies.

10. Claim 69 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is directed to algal organisms but several of the organisms while common in biomass development are not algal organisms such as *Mortierella* which is a fungus. It is not clear what is being claimed. One of skill in the art would not be able to ascertain the metes and bound of the invention. For purposes of prosecution, any algal organism or those listed in the claim apply.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 60-61, 63-65, 67-70, 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sugimoto (JP 06-070698) in view of Borrer et al. (U.S. Pat. 6036992) in view of Gladue et al. (WO 99/06585).

A human translation is provided; all references are to the translation.

Sugimoto teaches a method of making a feed additive for fish for improving meat quality and color. Sugimoto teaches formulating the feed additive by blending 100g of phospholipid with 0.1-10g of carotenoid. The additive is then added to the feed where the composition comprises at least 2g phospholipid (at least 2% of the feed) and at least 3mg carotenoid (at least .03% of carotenoid) per 100g of feed. The addition is 0.1g/100g feed to 10g/100g feed and the preferred range of phospholipid is 2g to 10g phospholipid/100g feed. The claimed range for the carotenoid in the feed is at least 3mg carotenoid in 100g of feed. The feed is applicable to farm-raised fish including Japanese flounder and grouper which are coldwater fish (known in the art as being below 20°C).

The carotenoids taught for use are astaxanthin, canthaxanthin, zeaxanthin, and beta-carotene, among others. Sugimoto also teaches a carotenoid complex (which would include more than one carotenoid) can be used. The phospholipid predominately used is lecithin and preferably in oil form. The phospholipid (e.g. lecithin) obtained in oil form can be purified by removing the oil with an organic solvent. If a powder form was used, oil such as vegetable, soybean, corn, olive, and others would be used to dilute the

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powder to form an oil to be added in the feed (see full translation, specifically Abstract, Claim 4, Paragraph 5-6,10-12)..

The carotenoid and phospholipid are mixed, then a binder and vegetable feed are added, and the feed is fabricated into pellet form to be used as feed. Sugimoto states that the amounts can change with concentration and fish stocks. There is also an oxidation study done at 20-24°C which is room temperature (ambient temperature).

Sugimoto does not expressly teach the duration of mixing or the temperature conditions of mixing. Sugimoto does teach that the carotenoid mix to be mixed into the phospholipid wherein absent criticality of the time duration, it would be obvious to one of skill in the art to mix the two components for a sufficient period of time until they were well incorporated. While Sugimoto does not expressly teach the temperature range during mixing, there is no express limitation on temperature by which the mixing would take place; as a result it would be obvious to one of skill in the art that the temperature would be room temperature (ambient). This is also supported by Sugimoto's oxidation study done at 20-24°C which is room temperature. One of skill in the art would be motivated to do this as Sugimoto has already tested the stability at room temperature and one would want the two components to be well mixed as directed by Sugimoto.

Sugimoto also does not expressly teach the lowest limitation of a carotenoid to be at least 1%, the phospholipid at least 5%, and the inclusion of a phospholipid with algae material with at least 20% fatty acid residues with 4 or more double bonds.

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Borrer et al. (U.S. Pat. 6036992) teaches that phospholipids can be derived from analogous sources including egg yolk, soy bean, and microbial single cell oils such as algal and fungal oils. Borrer teaches that the microbial single cell oils may be used, particularly for the AA and DHA fatty acid components of phospholipids (Col. 5 line 24-31).

Gladue et al. teaches that aquaculture feed need to be nutritionally balanced so that the fish larvae receive proper nutrition and DHA (docosahexenoic acid) significantly contribute to larval growth and survival which ultimately is acquired from algae. Gladue teaches that if sufficient DHA is provided to the larvae, the survival rate would increase, reducing the cost of farm-raised seafood. Gladue teaches that phospholipids with DHA phospholipids with residues with at least 20% fatty acid residues (intrinsically has 6 double bonds) are preferable for this result. Gladue also teaches that these can be derived from algal and fungal sources such as *Cryptocodinium*, *Mortierella*, and *Schizochytrium*. It is noted that Gladue also addresses the use of solvents such as hexane to extract the DHA phospholipid from the biomass (Page 1 line 27- Page 2 line 8, Page 3 line 11-Page 4 line 2, Page 4 line 18-Page 5 line 8, Page 9).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to adjust the amounts of the carotenoid and phospholipid, as suggested by Sugimoto, and use a phospholipid from an algae source as suggested by Borrer, particularly one with DHA phospholipids with residues with at least 20% fatty acid residues from microbial/algal sources as suggested by Gladue, and produce the instant invention.

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While Sugimoto does not expressly state the range of a carotenoid to be at least 1%, it is encompassed by the range taught by Sugimoto. Sugimoto teaches that the composition comprises at least 2g phospholipid (at least 2% of the feed) and at least 3mg carotenoid (at least 0.003% of carotenoid) per 100g of feed. Sugimoto also claims the carotenoid to be at least 3 mg per 100g of feed and the phospholipid to be at least 2g per 100g of feed. It would have been obvious to one of skill in the art to adjust and optimize the amount of carotenoid dependent on the animal to be fed or the components of the feed and particularly, to increase and optimized the amount of carotenoid to improve the color in the animal meat (e.g. salmon) as it is visually more appealing to consumers. The amount of phospholipid would increase proportionally as the additive requires blending 100g of phospholipid with 0.1-10g of carotenoid.

It is also obvious to one of skill in the art to utilize other analogous phospholipid sources such as algae, as Borror teaches that phospholipids can be drawn from several analogous sources such as egg yolk, soy bean, and algal oils. Borror also teaches that microbial single cell oils such as algal and fungal would be used for the AA and DHA fatty acid components of phospholipids. It would be obvious to one of skill in the art to use these algal and fungal phospholipids for the AA and DHA for the feed as Gladue et al. teaches that aquaculture feed need to be nutritionally balanced so that the fish larvae receive DHA (docosahexenoic acid) which significantly contributes to the larval growth and survival, and as the survival rates increase, it reduces the cost of farm-raised seafood. It also would be obvious to one of skill in the art to utilize phospholipids with DHA phospholipids with residues with at least 20% fatty acid residues (intrinsically has

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6 double bonds) as Gladue teaches that they are preferable for this result. Gladue also teaches that these can be derived from algal and fungal sources such as Crypthecodinium, Mortierella, and Schizochytrium which provide high levels of DHA phospholipids. It would be obvious to one of skill in the art to utilize as high a level of DHA in the phospholipid for improved survival rates such as at least 40% as Gladue teaches at least 20% absent evidence to the criticality of the DHA% of at least 40% in the phospholipid.

One of skill in the art would have been motivated to do this because it is routine in the art to optimize the feed to attain the desired improved color and qualities in the fish and greater and improved color in the animal meat such as salmon is visually more appealing to consumers and would produce more sales. The improved and greater concentration of color would be easily accomplished by the increase of the carotenoids in the feed. One of skill in the art would have been motivated to also use algal oil infused phospholipids as Borrer teaches them to be analogous with egg and soy sources with the benefit of AA and DHA fatty acid components and Gladue teaches that increased DHA in the feed, particularly DHA phospholipids with residues with at least 20% fatty acid residues (intrinsically has 6 double bonds) derived from algal and fungal sources such as Crypthecodinium, Mortierella, and Schizochytrium which provide high levels of DHA phospholipids, improves fish survival and lowers the cost of the farm-raised seafood which is desirable. It is also desirable to utilize as high a level of DHA in the phospholipid such as at least 40%, to have higher survival rates with the same or less product.

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12. Claims 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sugimoto in view of Borrer et al. (U.S. Pat. 6036992) in view of Gladue et al. (WO 99/06585) as applied to claims 60-61, 63-65, 67-70, 72 above, and in view of Place et al. (U.S. Pat. No. 6261590).

The teachings of Sugimoto in view of Borrer et al. in view of Gladue et al. are addressed above.

Sugimoto in view of Borrer in view of Gladue does not expressly teach coating the pellet with the mixture.

Place et al. teaches that drugs, vitamins, carotenoids, and/or pigments are usually added to animal feed (soap solution) before the spray drying process which would form the granules (e.g. powders, pellets, etc.). Place also teaches that the drugs, vitamins, carotenoids, and/or pigments could also be added to the feed (soap powder) after the drying step. The carotenoids and pigments included beta-carotene, cantaxanthin, astaxanthin, astaxanthin esters, zeaxanthin, among others.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to coat the pellets with the carotenoid mixture, as suggested by Place et al., and produce the instant invention.

It would be obvious to one of skill in the art as it is a known method for delivering actives to feed and one would have been motivated to do this because it is desirable for manufacturers to have several choices to modify and distribute the carotenoid/phospholipid additive depending on the degree of absorption and method of

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delivery used to produce the final product. If the additive is incorporated in the feed, the absorption would be delayed or time release dependent the components of the feed. If the additive was on the outer coat of the feed, then it would be immediate release in the digestive process. One would be motivated to use either method depending on the desired outcome. Additionally, many of the carotenoids taught in Place were those taught in Sugimoto showing compatibility and a reasonable expectation of success.

13. Claims 66 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sugimoto in view of Borrer et al. (U.S. Pat. 6036992) in view of Gladue et al. (WO 99/06585) as applied to 60-61, 63-65, 67-70, 72 above, and in view of Shao (Aquaculture pharmaceuticals and biologicals: current perspectives and future possibilities).

The teachings of Sugimoto in view of Borrer et al. in view of Gladue et al. are addressed above.

Sugimoto in view of Borrer in view of Gladue does not expressly teach the use of vortex mixing, high shear mixing, sonication, and molecular level mixing.

Shao teaches that the technology for premixes has not changed drastically over the last decades and that premixes in aquaculture for fish feed utilize high shear mixers/granulators to manufacture homogenous premixes of potent actives (Page 236, section 4.3-Development of premixes as a dosage form in aquaculture).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize known commercial mixers for combining the

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components, as suggested by Shao, and produce the instant invention. It would have been obvious to one of skill in the art to utilize the known methods of homogenizing the mix with commercial mixers such as high shear mixers to form a homogenous composition as Shao addresses the technology is long known and one of skill in the art would be motivated to use these high shear mixers as it is a long known reliable standard.

14. Claims 71 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sugimoto in view of Borrer et al. (U.S. Pat. 6036992) in view of Gladue et al. (WO 99/06585) as applied to 60-61, 63-65, 67, 70, 72 above, and in view of Robles Medina et al. (Downstream processing of algal polyunsaturated fatty acids).

The teachings of Sugimoto in view of Borrer et al. in view of Gladue et al. are addressed above.

Sugimoto in view of Borrer in view of Gladue does not expressly teach the use of a chlorocarbon or a lower alcohol. Sugimoto does teach purification of the phospholipid with an organic solvent and Gladue addresses the use of solvents for extraction.

Robles Medina et al. teaches the general knowledge of extracting and purification of algal polyunsaturated fatty acids. Robles Medina teaches that depending on polarity and fraction desired, there are several solvents available to achieve the desired result including chloroform, methanol, ethanol, and hexane. Robles Medina also teaches that with PUFA's with four or more bonds simpler equipment is needed, biocompatible solvents such as ethanol can be used, and milder conditions such as

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room temperature can be utilized (Overview of Lipid and/or fatty acids extraction and PUFA Concentration and Purification Techniques- Page 524-535 first paragraph).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to utilize known solvents for extraction and purification of algal PUFA, as suggested by Shao, and produce the instant invention. It would have been obvious to one of skill in the art to utilize the known methods of the art to use solvents such as methanol, ethanol, or chloroform dependent on the desired fraction and purity level for the composition to extract or purify the PUFA from algae. One would have been motivated to use to do so as these are known established solvents and methodologies that are standard in the art.

Response to Arguments

15. Claims 60-61, 63-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sugimoto (JP 06-070698) in view of Borrer et al. (U.S. Pat. 6036992) in view of Gladue et al. (WO 99/06585).

Applicant's arguments filed 6/15/2009 have been fully considered but they are not persuasive. In response to applicant's arguments against the references individually, such as Sugimoto not expressly teaching the inclusion of a phospholipids with algae material, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. In regards to Applicant argument that Borrer on the level of long chain fatty acids, this is not persuasive as Borrer was presented merely to show phospholipids can be derived from analogous

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sources including egg yolk, soy bean, and microbial single cell oils such as algal oils.

Borrer teaches that the microbial single cell oils may be used, particularly for the AA and DHA fatty acid components of phospholipids whereby only a specific section was addressed (Col. 5 line 24-31). Applicant's argument that the instant invention has unexpected and superior results is not persuasive. While the comparative is appreciated, it is not persuasive as the results are not sufficient to be considered to be unexpected. The art shows that PUFA's are highly stable and are present in krill oil wherein the carotenoid (e.g. astaxanthin) is more stable in the PUFA (krill oil). As a result, there would be more carotenoid for uptake in the presence of DHA (see Bustos et al. section 3.2 Stability of long chain PUFAs and astaxanthin).

Accordingly, the rejection is maintained.

16. Claims 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sugimoto in view of Borrer et al. (U.S. Pat. 6036992) in view of Gladue et al. (WO 99/06585) as applied to claims 60-61, 63-64 above, and in view of Place et al. (U.S. Pat. No. 6261590).

Applicant's arguments filed 6/15/2009 have been fully considered but they are not persuasive. Applicant's arguments are directed to Sugimoto, Borrer, and Gladue which are addressed above.

Accordingly, the rejection is maintained.

Conclusion

17. Claims 60-72 are rejected.

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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GH
/Zohreh A Fay/
Primary Examiner, Art Unit 1612